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GRUENBERG
PRELIMINARY AMENDMENT

- Grant
- (c) expanding the cells under conditions that produce high cell density to clinically relevant numbers; and
- (d) infusing the resulting cells into [a mammal] the mammal from which the material was collected.

A2

46. (Amended) A method of treating a patient infected with human immunodeficiency virus (HIV), comprising:
administering a clinically relevant number of [virally-purged] HIV-purged CD4⁺ cells to the patient, whereby symptoms of the infection are ameliorated.

Sub C

48. (Amended) A method of treating [patients] mammal with autologous regulatory immune cells, comprising:

(a) collecting a tissue or body fluid sample comprising mononuclear cells from the [a] mammal;

(b) [treating] activating the cells ex vivo to alter their cytokine production profile [to produce compositions containing];

(c) inducing cell proliferation and cell expansion to a clinically relevant number of regulatory immune cells; and

(d) reinfusing a sufficient number of the cells to alter the in vivo regulatory immune cell balance of the mammal.

A4

68. (Amended) A method for treating autoimmune disease, comprising [administering an therapeutically] administering a therapeutically effective amount of [the composition of claim 55] a composition comprising a clinically relevant number of human regulatory T cells, wherein the amount is sufficient to treat the autoimmune disease.

A5

70. (Amended) A method of preventing rejection of transplanted islets for treatment of insulin-dependent diabetes mellitus (IDDM), comprising:
administering a therapeutically effective amount of [the composition of, claim 55] a composition comprising a clinically relevant number of human regulatory T cells, wherein the amount is sufficient to prevent rejection of transplanted islets of Langerhans for the treatment of IDDM.

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95 71. (Amended) A method for [treating] treating allergies, infectious disorders or diseases, tumors or as vaccinating a human, comprising: administering a therapeutically effective amount of [the composition of, claim 55] a composition comprising a clinically relevant number of human regulatory T cell, wherein the amount is sufficient to treat the allergy, infectious disorder, tumor or to protect the human against infection or ameliorate the severity of an infection.

96 73. (Amended) A method of treatment of treating multiple sclerosis or insulin-dependent diabetes mellitus (IDDM), comprising: administering a therapeutically effective amount of [the composition of, claim 55] a composition comprising a clinically relevant number of human regulatory T cells, wherein the amount is sufficient to treat multiple sclerosis or IDDM.

97 110. (Amended) The method of [claim 1] claim 18, wherein the cells are CD4⁺ cells.

98 125. (Amended) The method of [claim 1] claim 18, wherein at least 10⁹ cells are administered.

99 131. (Amended) A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of [the composition of claim 42] a composition comprising a clinically relevant number of virally-pured CD4 + cells.

132. (Amended) A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of [the composition of claim 44] a composition comprising a clinically relevant number of virally purged CD4 + cells that are predominantly Th1-cells.

133. (Amended) A method for treatment of human immunodeficiency virus (HIV) infection, comprising administering an effective amount of [the combination of claim 45] a combination comprising a composition containing a clinically relevant number of CD4 + cells; and a composition containing a clinically relevant number of CD8⁺ effector cells.